UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

November 1, 1999

Robert F. Bischoff
Regulatory Manager
Dow AgroSciences, LLC
9330 Zionsville Road
Indianapolis, IN 46268

Dear Mr. Bischoff:

The Agency has received your September 2, 1999 comments on the Preliminary Health Effects Risk Assessment and your January 15, 1999 comments on the Preliminary Environmental Fate and Effects Risk Assessment for chlorpyrifos. The Agency had requested that comments be submitted to address errors in the risk assessments. Errors include, but are not limited to, mathematical, computational, typographic, or other similar errors.

We have carefully reviewed your comments and have revised the risk assessments accordingly. The attached table is a summary of your error-type and clarification comments and our responses to them.

Most comments received pertained to matters of interpretation and applicability of data and broader policy issues that are beyond the scope of this 30-day error correction comment period. However, these will be addressed as part of the 60-day public comment period starting on October 27, 1999.

If you have any questions, please contact Mark Hartman at (703) 308-0734.

Sincerely,

Kathy S. Monk, Chief
Reregistration Branch II
Special Review and
Reregistration Division

Attachment

Chlorpyrifos Preliminary Risk Assessment
Comment/Response Summary

Preliminary Health Effects Risk Assessment	
Comment	**Response**
GENERAL	
DAS contends that EPA performed some assessments based on canceled or inactive formulations or labels.	EPA evaluated products or labels currently considered active on the Agency's databases at the time of the assessment. As cancellation requests are submitted to the Agency and processed the appropriate adjustments will be made to future risk assessments.
DAS notes exposure to chlorpyrifos-methyl and TCP also contribute to TCP urinary measurements, and therefore that these measurements are conservative estimates of chlorpyrifos exposure.	EPA has clarified the language and also mentioned exposure to TCP resulting from environmental degradation of chlorpyrifos and chlorpyrifos-methyl as a contributing factor.
DAS requests that EPA incorporate the DAS-sponsored Mar Quest residential and specialty area market survey data into the assessment. DAS claims that EPA's assessment does not reflect actual market use of chlorpyrifos and overestimates exposure.	EPA will evaluate the Mar Quest survey for possible inclusion in a revised version of the preliminary risk assessment. It should also be noted that several additional scenarios have been evaluated for worker and residential exposure beside label maximums which provide a range of potential exposures from varied use of products.
DAS requests that EPA provide the registration number and trade name for all products assessed especially granule baits.	EPA added the registration number and/or trade name for products assessed where that information was available.
DAS notes that in 1994 there were 737 active products registered for use in the United States containing chlorpyrifos.	Currently, Agency databases show that there are 822 active products registered. This updated product number has been added to the document..
DAS is commercializing several labels, therefore EPA's assessment is not reflective of these labels.	EPA evaluated currently registered products that are accessible to homeowners. Chlorpyrifos is not a restricted use pesticide and there is evidence that concentrated products are available to homeowners.
TOXICOLOGY	

DAS notes that there are inconsistencies in the statement that "there are no comparable studies that examine age-related sensitivity at lower doses" other than Moser and Padilla (1998), and statements that the toxicity database is complete, and the Subdivision F Guideline studies provided no indication of increased sensitivity.	EPA has clarified that the toxicity database is complete according to Subdivision F Guidelines. However, EPA may require studies that test low doses of chlorpyrifos in the diet that compare neonates to adults to assess susceptibility. EPA is aware of recent studies presented at the Society of Toxicology (SOT) 1999 meeting that demonstrate that single oral doses of 0.45 to 1.5 mg/kg result in increased sensitivity of neonatal rats for plasma, diaphragm and cortex (brain) cholinesterase (ChE) inhibition relative to adults. These data are summarized in the preliminary risk assessment.
DAS notes inconsistent statements relating to increased sensitivity of young animals and completeness of the toxicity database.	EPA has clarified/harmonized text between the toxicity chapter, the risk assessment summary and FQPA documents with regard to increased sensitivity issue. EPA has clarified that the toxicology data base in accordance with Subdivision F Guidelines is complete, however, in light of FQPA, data may be needed to assess the susceptibility of infants and children at low doses.
DAS requests that the EPA report include information presented in DAS or DAS-sponsored publications which pertain mostly to toxicity and FQPA issues.	EPA will evaluate this data for possible inclusion in a subsequent version of the preliminary risk assessment.
DAS notes that EPA excluded information from the chronic dog study in the discussion of subchronic studies.	EPA has included the chronic dog findings in the subchronic toxicity discussion.
DAS notes that Szabo et al. (1988) subchronic oral exposure study did not test a dose of 10 mg/kg/day as stated in the assessment.	EPA has added a reference to the Crown et al. (1985) study to the assessment that refers to effects at 10 mg/kg/day.
DAS notes that the effects noted in the discussion of the Szabo et. al. study did not occur at 1 mg/kg/day, but rather at 15 mg/kg/day.	EPA has revised the text reference of 1 mg/kg/day to 15 mg/kg/day.
DAS notes the need for minor edits in the discussion of the developmental neurotoxicity study, e.g. change "to" to "by"; remove word essentially, change 22.3 to 23.3, remove 1 hour, add "up to" before 9 days and other minor edits in the toxicology section of the assessment.	EPA has corrected these typographical errors.
DAS notes that EPA should provide, in reference to chronic exposure, the reference for the statement "mice appear to be the least sensitive". DAS notes that the degree of plasma, RBC and brain ChEI following repeated doses are nearly identical in rats (Szabo et al. 1988) and mice (Davies et al. 1985).	EPA has added the reference, Gur (1992), to support that mice are the least sensitive species following chronic oral exposure.

DAS notes the need for a clarification of dose level, the need to specify plasma ChE, and the need to elaborate on oxon half-life in EPA's discussion of the acute pharmacokinetic study.	EPA has clarified these points.
DAS notes that although the acute oral rat study measured NTE, it was not designed specifically to measure the potential of chlorpyrifos to inhibited NTE as EPA states.	EPA has rephrased the sentence.
DAS notes that the anticipated completion date for the review of the neurotoxicity study of sensory electrophysiology is not correct.	EPA has removed this statement on anticipated completion date.
DAS recommends removing the word "reportedly", requests clarification of a statement, and disagrees with the Agency attributing the greater inhibition of plasma versus RBC activity in the Coulston study on human oral exposure to the "limited number of subjects and variability of the cholinesterase assay methodology".	EPA has removed the word "reportedly" and has removed the referenced paragraph referring to the Coulston study because EPA agrees the paragraph is poorly worded and confusing.
DAS suggests clarifying the sentences in the text that refer to study description and results for the study that complements the developmental neurotoxicity (DNT) study.	EPA clarified/corrected the sentences.
DAS requests that additional details on the reproductive toxicity study be presented in the toxicity chapter	EPA has elaborated on the study findings discussion in the assessment.
DAS states that EPA's discussion of the Capodicasa et al. (1991) study regarding delayed polyneuropathy is misleading, and suggests additional language be added. In addition, DAS suggests the Agency also discuss the Richardson et al. (1993) study which extends the Capodicasa et al. (1991) study.	EPA clarified the language in the discussion of the Capodicasa study. The Agency will include the Richardson study in the revised risk assessment following the public comment period.
DAS requests additional details be provided in the text in the discussion of the acute rat neurotoxicity study.	EPA has clarified the text discussion of this study.
DAS suggests including updated acute toxicity studies rather than the older pre-GLP studies summarized in Table 1 of the Toxicology Chapter.	These data have been incorporated into the EPA report.
DAS requests that EPA consider additional studies (Chakraborti et al. 1993, Pope and Liu 1997 and Liu et al. 1999) conducted at lower dose levels and repeated administration that demonstrate that the neonate is not more sensitive than the adults in DAS's opinion.	EPA's HIARC committee considered the Chakraborti et al. (1993) study and the Pope and Liu (1997) study. They are discussed in the December 7, 1998 HIARC Report in its recommendation of the FQPA safety factor. The Liu et al. (1999) study was published following the most recent HIARC meeting, and therefore, has not been considered by the Agency, but will be considered in future meetings of the committee.

DAS notes that the data from a subchronic rat feeding study do not support that the hematological alterations are suggestive of anemia.	EPA has removed reference to anemia.
RESIDENTIAL\PCO ASSESSMENT	
DAS disagrees with EPA's analysis of Turf Treatment at the higher rate than used in the biomonitoring study. DAS claims that EPA's assessment of broadcast treatment by a LCO at a higher rate than evaluated in the biomonitoring study is confused with perimeter treatments by PCOs (i.e., LCOs are not permitted to broadcast apply chlorpyrifos as the higher rate evaluated by EPA).	EPA has deleted the analysis for the higher rate of 0.12% at 10 gallons/1000 ft2 and agrees this rate is only applicable to perimeter treatments and not broadcast treatments. However, the label allows broadcast treatment of 0.12% at 4 gal/1000 ft2, which is twice the application rate evaluated in the study, therefore this rate will be included in the assessment.
DAS disagrees with bridging from assumptions from wettable powder mixing and loading to use of a dust formulation to assume that total dust exposure is comprised of 99% dermal and 1% from inhalation.	EPA revised the dust analysis, and used only exposure data from the scientific literature with normalization for chlorpyrifos exposure. Therefore, these bridging assumptions were not used in the risk assessment
DAS requests additional information on specific use scenario assumptions, especially on exposure from dust application, and granular bait scenarios.	EPA has provided additional details and will reference the appropriate EPA reviews that contain the details of each exposure assessment.
DAS contends it is inappropriate to extrapolate the biomonitoring results of a homeowner for the ready to use (RTU) product to a PCO, because PCOs refrain from using RTU liquids.	EPA removed the analysis for PCOs based on the homeowner biomonitoring data.
DAS notes that EPA should specify "adult" mosquitocide	EPA has clarified the text.
DAS is not clear if the granule bait is insect food or just non-food (clay, corn cob etc) granular formulation	EPA evaluated a non-food granular formulation, using the application rate of the DAS submitted study MRID 4416710. EPA has removed the word "bait" for clarification purposes.
DAS notes that the statement on p 32 should state that 90% of the label rate was applied not 75%.	EPA has clarified that although the study intended to apply 1.8 lb ai/acre which represents 90% of the maximum label rate of 2 lb ai/acre, the deposition measurements in the study indicate that only 75% of the theoretical recommended label rate was applied.
DAS notes that the draft SOPs indicate the exposure period should be two hours instead of four hours, and that the assessment of yard and ornamental sprays be revised.	The Yard and Ornamental spray assessment was based on analogy to the results of the DAS-biomonitoring studies where a four hour exposure was evaluated, but only two of these hours consisted of dermal contact with the turf. The other two hours were spent on a blanket during picnicking and sunbathing. The draft residential SOPs recommend two hours of dermal contact, therefore, the sentence has been revised to clarify this fact.
DAS suggested minor edits on % a.i. formulated products used in the assessment.	EPA has made revisions except for dust formulations which contain up to 7% a.i. (EPA Reg 13283-17).

DAS notes that the statement "the diluted product was sprayed onto the tarp using a hand held sprayer" is incorrect, and that the diluted product is sprayed on the soil and covered with the tarp prior to pouring the concrete slab	EPA has corrected the study description.
DAS notes that chemically resistant footwear, an extra coverall or a chemically resistant apron are currently required by the Dursban TC speciality termiticide concentrate label as per Pesticide Regulation Notice PRN 96–7	EPA has removed the statement that these PPE are not required by the label.
DAS notes that a pet collar exposure study is underway at Mississippi State by Dr. Janice Chambers	EPA is aware of the study, and makes reference to this study under the results of the pet collar evaluation, but will also note the study in the exposure section.
DAS believes that the dermal dose lacks the 0.03 dermal absorption factor for long-term PCO with PPE scenario	EPA has already adjusted the unit exposure for 0.03 dermal absorption during the evaluation of the biomonitoring study, and has added a footnote to clearly state this fact.
DIETARY ASSESSMENTS	
DAS notes there are no tolerances for popcorn, garlic and garden beets, therefore these commodities should not be included in the dietary analysis.	EPA has omitted these commodities (popcorn, garlic, beets, beet greens) from the exposure assessment.
DAS noted errors in the construction of RDF files for apples, leafy greens and strawberries.	EPA has corrected the RDF files. The RDF files for cabbage and strawberries were correct. The description in the text was corrected. The apple RDF was correctly described and had a rounding error of 1 digit. This error has been corrected.
DAS notes that percent food handling establishments treated should be included in the analysis.	EPA has incorporated percent food handling establishments treated in the chronic dietary assessment.
DAS notes the assessment approach contains illogical assumptions that greatly over estimate even the chance of exposure. For example, the model simulation assumes that treatment to an FHE produced residues in all tap water...etc.	EPA has removed tap water from the chronic dietary assessment.
DAS notes that EPA failed to include values used for the limit of detection (LOD) and the average residue values for each crop prior to incorporation of percent crop treated so DAS can verify the anticipated residues used in the dietary assessment.	EPA has included the LOD for the FDA method in the assessment.
DAS requests that cranberry data obtained from the Cranberry Institute be used in the dietary exposure assessment.	EPA has revised both acute and chronic dietary assessments to incorporate the recently received cranberry data in exposure analysis.
CHEMISTRY	

DAS notes that some listed products have been canceled or that the product names have been changed.	EPA has made the necessary corrections.
DAS notes some SLNs were not listed or incorrectly listed.	EPA has corrected SLNs, and added SLNs to the existing list.
DAS notes that grape pomace is no longer in Table 1, therefore the reassessed tolerance should be deleted. Also, Table OPPTS 860 no longer lists grape pomace as a feedstuff.	EPA has deleted grape pomace, and made other needed corrections.
DAS notes that mint leaves and stems were analyzed, not dried tops. Therefore, additional data are not required.	Fresh mint was analyzed in MRID #00034031. Residue Chemistry Chapter has been revised to reflect this.
DAS noted melting point of technical chlorpyrifos is 41.5 to 42.5 C (not 41.5 to 43.5 C)	Typographical error has been corrected
AGRICULTURAL\OCCUPATIONAL EXPOSURE	
DAS requests that baseline assessments not be included in the report.	Baseline assessments are usually included in the first draft of a risk assessment so that PPE could be reduced if appropriate. In the case of chlorpyrifos, none of the scenarios had MOEs > 100 at baseline. Therefore, baseline assessment has been deleted from the document.
DAS comments that the WP formulation should be assessed as packaged in water soluble packets.	The WP are assessed in water soluble packets under the headings of engineering controls. The open bag packaging analysis has been removed.
DAS notes an error in the stump treatment application rate used in the assessment	The rates used for assessing this use have been corrected.
INCIDENT REVIEW	
DAS believes that the use of the term “Poison Information Specialist” leaves the impression these specialists are uniformly certified by AAPCC.	Most of the cases (83%) submitted to the Toxic Exposure Surveillance System (TESS) are submitted by certified Poison Control Centers (PCCs) (Toby Litovitz, personal communication). A clarification has been added to reflect the fact that most cases are handled by certified centers which require their specialists to complete a training program and become certified and that some centers do not have this requirement.
DAS believes that the figures for number of unintentional pesticide exposures to organophosphates is inconsistent with published data.	DAS appears to assume that only exposures involving “organophosphates only” are included in the analysis. This is not the case. All exposures to single products that include the active ingredient chlorpyrifos are included.

DAS believes that the number of life-threatening cases in the Table on page 6 differs from the text on page 4 of the incident assessment document.	The difference noted by DAS is due to the fact that page 6 includes only cases occurring at a residential site and only products that could be categorized as being more likely to be used by a consumer or PCO with reasonable certainty.
DAS believes the statement about case review gives the impression that the actual patient record was reviewed.	EPA believes that other statements in this document make it clear that PCCs obtain information by telephone interview. However, EPA has added the term "medical record" to clarify.
Preliminary Ecological Risk Assessment	
DAS indicates that the Lorsban 15G formulation was a clay-based granule and not a corncob-based granule as cited in the risk assessment.	EPA has corrected the assessment text to reflect this fact.
DAS indicates that EPA used out-of-date data for the quantitative use information and cited corrections based on a more current EPA use assessment report.	EPA has updated the assessment based on this newly available updated information.
DAS indicates that chlorpyrifos use on corn is primarily as a granular formulation and only about 7 % (8 % is the likely maximum) is a liquid formulation.	EPA assessed risks for both formulations on corn and will change the liquid usage from "8 percent" to "about 7 %."
DAS states that "The maximum use rate for all at-plant applications of Lorsban 15G insecticide on corn is 1.2 oz. a.i. per 1000 feet of row." The use rate is not 1.2 to 2.4 oz. a.i. per 1000 feet of row cited in the risk assessment or the 2.4 oz. a.i. per 1000 feet of row in EPA's risk assessment.	EPA has closely reviewed the labels and found that there are instructions for certain pests that call for a use rate up to 1.8 oz. ai/1000 feet of row. The risk assessment for the granular use at-plant has been corrected to the maximum use rate of 1.8 oz. ai/1000 feet of row.
DAS provides updated use rates for corn.	EPA has incorporated these new rates into its assessment as appropriate. However, the analysis of the 0.5 and 1.0 formulation analysis for homeowner use were retained.
DAS indicates that no tolerance exists for chlorpyrifos on rapeseed.	The section in the assessment on rapeseed has been deleted.
DAS indicates that chlorpyrifos is not applied to cotton as a pre-plant treatment and that there is not a post-plant application rate of 0.5% .	The pre-plant analysis for cotton has been deleted from the assessment. The 0.5% application rate analysis has also been deleted.
DAS indicates that the Special Local Needs registration for Lorsban 50W use on soybeans in Indiana, Michigan and Ohio has expired.	Reference to this SLN use has been deleted.
DAS indicates that Lorsban use on mushrooms was discontinued and will not be supported by DAS for reregistration.	Since the tolerance will not be supported, reference to chlorpyrifos use on mushrooms has been deleted.

DAS indicates that the volume of spray for dormant tree treatments needed to penetrate tree bark requires ground application and can not be achieved by aerial spray. And DAS indicated that the use of Lorsban 50W on macadamia nuts is limited to dormant treatment and there is no foliar application registered.	These changes have been made in the assessment.
DAS suggests that mint is more appropriately placed in the category of cover crops than in the vegetable category.	This change has been made in the assessment.
DAS indicates that EPA failed to mention the required buffer zones and application restrictions for ground and aerial applications of Lorsban 4E-SG.	The buffer zone and application restrictions for this product have been incorporated into the assessment.
DAS indicates that the typical chlorpyrifos use on peanuts is applied at the early pegging growth stage and is not applied at the at-plant stage assessed by EPA.	This change has been incorporated in the assessment.
DAS indicates that the typical use rate for tobacco should be 2 lbs ai/A, instead of the 2.2 lbs ai/A in EPA's risk assessment.	This change has been incorporated in the assessment.
DAS indicates that the typical use rate used by EPA for citrus at 2.4 lbs ai/A is incorrect and should be a single air-blast, foliar application to oranges in California at 6.0 lbs ai/A.	EPA has amended the risk assessment for the typical use on oranges in California to 6.0 lbs ai/A.
DAS reports that rather than the 2,000 to 5,000 ppm cited by EPA, the highest label concentration of chlorpyrifos applied as a non-agricultural use is 20,000 ppm for termiticide uses with underground utility cables and conduits, utility poles and fence posts, and both pre- and post-construction termite control when used in accordance with the variable volume termiticide use directions for selected visible applications.	This change has been incorporated in the assessment.
DAS indicates that perimeter treatments at concentrations of 0.03 to 0.12 percent are limited to 10 feet away from a structure and to a height of 2 or 3 feet, rather than the 15 feet cited by EPA. Uses at high concentrations of 0.5 % (5,000 ppm) are applied to "specific areas such as cracks and crevices along walkways, patios, windows, and door frames or other areas where insects may congregate or can gain entrance to the structure."	EPA has determined that the perimeter treatment is a band 6 to 10 feet around a structure at a concentration of 0.0325 percent chlorpyrifos (i.e., 325 ppm solution) and an outside surface treatment at 0.525 percent (i.e., a 5,250 ppm solution). The risk table and text have been corrected.
DAS indicates that the calculation of the concentration for perimeter treatments for 0.03 to 0.06 percent formulations should be 300 to 600 ppm, not 3,000 to 6,000 ppm.	EPA has made this correction to the assessment.

DAS indicates that EPA erroneously made reference to micro-encapsulated granules, which DAS terms a micro-encapsulated formulation that forms a suspension of 15-20 micron particles in water.	EPA has made this correction to the assessment.
DAS indicates that homeowner use of concentrated Dursban are not as high as 12,000 ppm ai in water. DAS indicates that "The more typical application concentration is 2,800 - 3,700 ppm."	EPA identified the maximum use concentration as 5,250 ppm and revised the risk assessment to reflect this correction.
DAS indicates that EPA's reference to applications of 8 lbs ai/A refers to sod farms to control fire ants and is not a residential lawn use.	EPA has clarified the wording.
DAS indicates that maximum chlorpyrifos application rate on ornamentals is 1% (10,000 ppm) for beetle control (10 2/3 oz./gal.), rather than the 8,000 ppm in EPA's assessment. DAS states that the vast majority of ornamental uses are applied at 600 to 1200 ppm.	EPA has made this correction to the assessment.
DAS expresses concern that EPA cited monitoring data which showed that pet shampoo treatments posed risks to aquatic organisms from POTW effluents, when all pet uses have been voluntarily deleted.	EPA has changed the text to reflect that pet shampoo uses have been canceled.
DAS indicates that the chemical structures for chlorpyrifos and TCP in Appendix I are in error.	EPA corrected the spacings so that the structures are in alignment.
DAS identifies the absence of test duration in the aquatic toxicity tables.	Aquatic toxicity tables were modified to specify the duration of the exposure for the toxicity values.
DAS indicates that EPA did not include the citation of the Foe (1995) document in the reference section.	This citation has been added to the reference list.
DAS corrects the Genus spelling for the rock dove.	This typographical error has been corrected.
DAS indicates that the effects seen in the mallard duck reproduction study were not at the NOEC, but at the LOEC.	This error has been corrected in the text of the assessment.
DAS comments that the starling is a passerine species and had been omitted for the list of passerine species.	The text has been corrected to clarify the sentence.
DAS comments that the terminology "consistent reduction" is a not correct in the discussion of two earthworm field studies.	The text has been corrected to clarify the sentence.
DAS states that the toxicity classification for amphibians is unclear.	The text has been corrected to clarify.
DAS states that carcasses with the presence of chlorpyrifos should be classified as "likely" to be treatment-related.	The text has been corrected to clarify.
DAS corrects the summary tables for wildlife observations for the three chlorpyrifos field studies.	The tables have been corrected to reflect these changes.

DAS indicates that the authors of the large pen simulated field study concluded the LOEC was based only on abnormal behavior and not mortality.	The text has been corrected to accurately reflect the study authors' conclusions.
DAS indicates that the discussion of terrestrial incident reports and additive toxicity is not accurate in terms of inclusion of the pesticides listed.	The text has been corrected.
DAS identifies a sentence which should be removed from one paragraph and be the heading for the following paragraph in the incident section.	The text has been corrected.